UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	MDL No. 2875 Honorable Robert R. Kugler, District Court Judge Oral Argument Requested
This Document Relates to All Actions	

DEFENDANTS' MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFFS' MOTION TO PRECLUDE OPINIONS OF DEFENSE EXPERT JOHN M. FLACK, M.D., M.P.H.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Other Authorities

Pursuant to Federal Rules of Evidence 104, 403, and 702, Defendants' Executive Committee, on behalf of all Defendants in this litigation, submit this memorandum of law in opposition to Plaintiffs' Motion to Preclude Opinions of Defense Expert John M. Flack, M.D., M.P.H. (the "Motion") and state as follows:

INTRODUCTION

Plaintiffs identify no legally cognizable ground to exclude Dr. Flack's opinions under Rule 702. Dr. Flack is a clinician, a researcher, and leading scholar in the field of hypertension. He is the President of the American Hypertension Specialist Certification Program and serves as an Associate Editor for Hypertension, the premier hypertension journal in the world. He has over 40 years of experience as a practicing physician and holds a lifetime certification as a Specialist in Clinical Hypertension by the American Society of Hypertension and a lifetime certification in Internal Medicine from the American Board of Internal Medicine. He also has an extensive clinical practice, having treated thousands of hypertensive patients in his career and prescribed antihypertensive medications to approximately 4,000-5,000 patients between 2012-2018. Plaintiffs do not challenge Dr. Flack's qualifications to opine on hypertension-related issues, or the helpfulness of these opinions (including his "simple explanations of the various medications that can be prescribed to treat hypertension," as Plaintiffs couch them) to the jury. *See, e.g.*, Motion at 5. Instead, Plaintiffs seek to expand the requirements of Rule 702 by suggesting that Dr. Flack

must prove the correctness of his opinions (with affirmative evidence no less), rather than establishing the reliability of his methodology. This, of course, is not the standard under Rule 702. Rule 702 simply requires that the expert's methodology be reliable—which Dr. Flack's is.

Dr. Flack's opinion about the efficacy of the recalled VCDs is based on his analysis of the literature, his extensive background as a researcher and peer reviewer in the field of hypertension, and his clinical practice over his forty-year career. That no epidemiological studies exist comparing the efficacy of VCDs containing nitrosamines to VCDs not containing nitrosamines does not render Dr. Flack's methodology unreliable. In fact, the Third Circuit has repeatedly held that a medical expert need not cite epidemiological studies as part of a reliable methodology. And, as Dr. Flack explained, the lack of studies showing that the presence of trace nitrosamines impacted the efficacy of VCDs *is evidence* that it did not.

Plaintiffs' attack on the clinical basis for Dr. Flack's opinion regarding the efficacy of the recalled VCDs misses the point completely. Dr. Flack did not observe a change in clinical effectiveness of VCDs in *any* of his patients during the time the VCDs containing NDMA and NDEA were on the market. He did not need to determine which of his patients took drugs containing NDMA or NDEA to opine on his observation that there was no change in the clinical effectiveness of the VCDs in his patients *across the board* during the relevant period. Plaintiffs' quibbles with Dr.

Flack's well-grounded and well-reasoned opinion based on his clinical observations are, at most, issues to be explored on cross-examination, not grounds for exclusion.

The same is true for Plaintiffs' criticisms of Dr. Flack's opinion that the valsartan recalls did not negatively impact hypertension patients. Dr. Flack has offered a narrow opinion: that the recall did not have adverse clinical outcomes on patients. That is, the therapeutic benefit to patients was not affected by the recall because alternative medications were readily available where needed and just as effective. Plaintiffs seek to expand the scope of Dr. Flack's opinion to attack it. But the focus of Dr. Flack's opinion is the lack of any negative *clinical* effects of the *recall*, not any increased risks associated with exposure to valsartan containing nitrosamines. Plaintiffs' contention that Dr. Flack "cherry-picked" evidence thus misses the mark. And Dr. Flack's point about the FDA's estimate of the increased risk of cancer for patients taking the highest dose of NDMA-containing valsartan is that, even accepting this estimate, the pool of patients at *any* increased risk is reduced when patients' practices in using antihypertensive medications (specifically, the duration for which they use them) are considered. Plaintiffs' arguments about the risks posed by the recalled VCDs have nothing to do with Dr. Flack's opinions.

Finally, Dr. Flack is well-qualified to opine that the third-party payors would have paid for alternative medications if the recalled VCDs had been unavailable. He does not need to have experience working for a third-party payor to offer this

opinion. He is a clinician with extensive experience treating hypertension and bases his opinions on hypertensive patients' need for medications to adequately control their blood pressure. And this opinion is plainly relevant to Plaintiffs' allegations about their damages, and therefore fits the case.

In sum, Plaintiffs have identified no valid grounds to exclude Dr. Flack's testimony under Rule 702 or *Daubert*, and thus Defendants respectfully request the Court should deny their Motion.

LEGAL STANDARDS

Rule 702 provides that a witness who is "qualified as an expert by knowledge, skill, experience, training, or education" may offer opinions in a case if (i) the expert's "scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue"; (ii) "the testimony is based on sufficient facts or data"; (iii) "the testimony is the product of reliable principles and methods"; and (iv) "the expert has reliably applied the principles and methods to the facts of the case." *See* Fed. R. Evid. 702. Applying the Supreme Court's guidance in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 589 U.S. 579 (1993), the Third Circuit has explained that "[w]here a party objects to the admissibility to proffered expert opinion testimony, the court must examine '(1) the qualifications of the expert, (2) the reliability of the process or technique the expert used in formulating the opinion, and (3) the "fit" between the opinion and the facts

in dispute.'" *R.D. v. Shohola, Inc.*, 2019 U.S. Dist. LEXIS 198035, at *7 (M.D. Pa. Nov. 15, 2019) (quoting *Buzzerd v. Flagship Carwash of Port St. Lucie, Inc*., 669 F. Supp. 2d 514, 519 (M.D. Pa. 2009) (citing *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 741-47 (3d Cir. 1994) ("*Paoli II*")).

"*Daubert* neither requires nor empowers trial courts to determine which of several competing scientific theories has the best provenance. It demands only that the proponent of the evidence show that the expert's conclusion has been arrived at in a scientifically sound and methodologically reliable fashion." *U.S. v. Mitchell*, 365 F.3d 215, 244 (3d Cir. 2004) (quoting *Ruiz-Troche v. Pepsi Cola Bottling Co*., 161 F.3d 77, 85 (1st Cir. 1998)). In other words, "any deficiencies in the evidence supporting [an expert's] conclusions and the correctness of those conclusions are relevant to the weight that his opinion should be given, not to its admissibility." *State Farm Fire & Cas. Co. v. Hartman Contrs.*, 2017 U.S. Dist. LEXIS 75967, at *22 (E.D. Pa. May 17, 2017); *see also Broe v. Manns*, No. 15-985, 2016 WL 7048988, at *4 (M.D. Pa. Dec. 5, 2016) ("Any disagreement plaintiffs have with the expert can be dealt with through cross-examination, presentation of contrary evidence and proper jury instructions"); *In re Asbestos Prods. Liab. Litig*., 714 F. Supp. 2d 535, 544 (E.D. Pa. 2010) (noting defense experts' disagreement with plaintiff's expert's explanation for the lack of epidemiological studies supporting his opinion and concluding that "this does not negate the fact that [the expert's] opinions

are based on generally accepted scientific methods and procedures, and that he gave a reasoned explanation for his preferred methodology"); *In re Diet Drugs Prods. Liab. Litig.*, MDL No. 1203, 2000 WL 962545, at *13 (E.D. Pa. June 28, 2000) (finding that disagreement with the methods used by an expert is a question that "goes more to the weight of the evidence than to reliability for *Daubert* purposes").

ARGUMENT

I. DR. FLACK'S OPINION THAT PATIENTS DERIVED THERAPEUTIC BENEFITS FROM VALSARTAN, IRRESPECTIVE OF THE PRESCENCE OF TRACE AMOUNTS OF NITROSAMINES, IS THE RESULT OF A RELIABLE METHODOLOGY.

Dr. Flack opines that the value of VCDs to patients, from a clinical perspective, is not affected by the presence of NDMA or NDEA. *See* Expert Report of John Flack, M.D., M.P.H., dated Dec. 19, 2022 ("Flack Report"), Mot. Ex. 1 at 10. Dr. Flack based this opinion on: (1) his knowledge, review, and analysis of the current scientific literature; (2) his impeccable qualifications and experience as a researcher and scholar in the field of hypertension; and (3) his extensive clinical practice. In other words, Dr. Flack is qualified to offer this opinion, and it is the product of a reliable methodology as required by Rule 702 and *Daubert*. Defendants respectfully request the Court deny Plaintiffs' Motion.

A. The Lack of Scientific Evidence That the Efficacy of VCDs Is Impacted by Trace Levels of Nitrosamines Supports Dr. Flack's Opinions.

Plaintiffs' argument that Dr. Flack "must have affirmative evidence supporting his opinion [in the form of epidemiological studies], not a lack of evidence supporting the counter opinion" is not only glaringly unsupported, it has been specifically and repeatedly rejected by district courts interpreting Third Circuit precedent. *See, e.g.*, *Hoefling v. U.S. Smokeless Tobacco Co., LLC*, 576 F. Supp. 3d 262, 274 (E.D. Pa. Dec. 21, 2021) ("Expert testimony '*should not be excluded simply because there is no literature on point*' provided there are 'other factors that demonstrate the reliability of the expert's methodology.") (emphasis added) (quoting *Schneider v. Fried*, 320 F.3d 396, 406 (3d. Cir. 2003). For example, in *State Farm Fire & Cas. Co.*, after holding that the proffered expert reliably applied the scientific method, the court rejected the argument that the opinion lacked evidentiary support as a basis for exclusion. 2017 U.S. Dist. LEXIS 75967, at *22. The court observed that "any insufficiency in the evidence supporting [the expert's] conclusions or errors in those conclusions can be covered in cross-examination at trial." *Id.* at *22-23 ("As long as an expert's scientific testimony rests upon good grounds, based on what is known, it should be tested by the adversary process—competing expert testimony and active cross—examination. . . .") (citing *Mitchell*, 365 F.3d at 244). In *In re Asbestos Prods. Liab. Litig.*, the court held that *even where a medical expert*

is opining on causation (which Dr. Flack repeatedly confirmed he is not), "[e]pidemiology studies are not per se required, and may not be needed, if an expert offers a reliable causation opinion through the use of some other valid scientific methodology." 714 F. Supp. 2d at 544 (citing *Heller v. Shaw Indus.*, 167 F.3d 146, 155-56 (3d Cir. 1999)). The *In re Asbestos Prods. Liab. Litig*. court observed that the challenged expert relied on several sources to support his opinion, including case studies, animal studies, and fiber migration studies. *Id.* at 543. The court then noted that the expert did not ignore relevant epidemiological studies; rather, he offered an explanation for the absence of certain studies. *Id.* at 544. In the face of his "reasoned explanation for his preferred methodology," any dispute about that methodology was a question for the jury. *Id.*

Here, similar to the argument the court rejected in *In re Asbestos Prods. Liab. Litig*., Plaintiffs contend that Dr. Flack's opinion on the efficacy of VCDs containing trace amounts of NDMA or NDEA should be excluded because Dr. Flack "admitted that he could not find any clinical trial, any epidemiology study or any scientific literature whatsoever that compares the effectiveness of treating hypertension with VCDs versus valsartan without NDMA or NDEA." *See* Motion § I.A. Of course, Dr. Flack "could not find" any such studies because there are none. *See, e.g.*, Transcript of John M. Flack, M.D., M.P.H., dated Feb. 1, 2023, (Mot. Ex. 2) ("Flack Dep.") 60:21-61:5; Flack Rep. at 10 ("There is no available evidence to prove, *or even to*

suggest, that NDMA or NDEA has any detectable effect on blood pressure or the functioning of the cardiovascular system or kidneys, or any diminution of the blood pressure lowering effect or target-organ protection of VCDs") (emphasis added). Plaintiffs' suggestion that Dr. Flack's methodology is unreliable in this context (where no studies exist) would render any medical expert opinion unreliable when it is so well-supported by other scientific knowledge that no one has bothered to do an epidemiological study to further prove it. This suggestion is not only illogical; it ignores Third Circuit precedent. *See, e.g.*, *Hoefling*, 576 F. Supp. at 274; *State Farm Fire & Cas. Co.*, 2017 U.S. Dist. LEXIS 75967, at *22; *In re Asbestos Prods. Liab. Litig*., 714 F. Supp. 2d at 543-44.

Dr. Flack is a leading researcher in the field of hypertension who regularly researches and analyzes medical and scientific literature and forms well-reasoned conclusions based on the available literature. *See* Flack Rep. at 2. Dr. Flack applied this standard methodology here. *Id.*; Flack Dep. 60-4-61:5. As he explained, he regularly reviews journals and manuscripts in his role as Associate Editor at Hypertension, and he also specifically researched whether there were any relevant studies comparing the efficacy of VCDs with trace amounts of NDMA or NDEA to VCDs without NDMA or NDEA. *See* Flack Dep. 52:18-53:4; 60:21-61:5. Plaintiffs do not criticize the scope or content of Dr. Flack's knowledge or the studies he considered. Instead, they take issue with the fact that no epidemiological study was

uncovered and with the conclusion Dr. Flack draws from this lack of evidence. But this alone is not a ground for exclusion. *See, e.g.*, *Hoefling*, 576 F. Supp. 3d at 274; *In re Asbestos Prods. Liab. Litig.*, 714 F. Supp. 2d at 544.

Indeed, "other factors" demonstrate that Dr. Flack employed a reliable methodology. *See Hoefling*, 576 F. Supp. 3d at 274 (holding that expert testimony "should not be excluded simply because there is no literature on point" where "other factors" demonstrate the reliability of the expert's methodology). As a peer reviewer, Dr. Flack reviews manuscripts for "50-plus" journals and reads manuscripts every week in the field of hypertension. *See* Flack Dep. 60:15-20. In his work as a peer reviewer, editor, and through his research for this case, Dr. Flack has not come across any article establishing that the presence of NDMA or NDEA in valsartan affects its clinical efficacy:

> Q: And through that work and through your research in this case, have you come across any article that – that demonstrated [that] the presence of trace amounts of NDMA or NDEA in valsartan had an effect on its clinical efficacy?
>
> A: I've searched for that and I have not been able to find it.

Flack Dep. 60:21-61:5. Dr. Flack also reviewed and considered FDA guidance that supports the same conclusion:

> The Food and Drug Administration had massive amounts of data and very talented people in multiple areas and never issued a mandatory recall. The recall was voluntary and they issued guidance to practitioners and health systems and pharmacies on how to deal with this. The approach that they took was not consistent with being

> overreactive and not taking your time making a transition, *including getting specific guidance to continue to take the drug until such time a transition was made*.

Flack Dep. 15:1-10 (emphasis added). The body of evidence Dr. Flack considered, coupled with his extensive experience treating patients using these medications, shows his methodology to be reliable and his conclusions about the efficacy of VCDs containing trace nitrosamines to be well-reasoned. Accordingly, Plaintiffs' Motion to preclude these opinions should be denied.

B. Dr. Flack's Clinical Observations Are a Reliable Basis for his Opinions.

Dr. Flack's opinions about the efficacy of recalled nitrosamines are bolstered by his clinical observations, which Plaintiffs futilely attempt to discredit. Plaintiffs' assertion that Dr. Flack's observations are not reliable "without having any knowledge as to which of his patients took VCDs with NDMA or NDEA versus which of his patients took [] valsartan without NDMA or NDEA" (*see* Motion § I.B.) is, again, both illogical and unsupported. Dr. Flack's opinion is based on his clinical observations indicating that there was no reduction in the clinical benefits of VCDs in *any* of his patients during the time at issue, when the recalled VCDs were available. *See, e.g.*, Flack Rep. at 11 ("[I]n other words, I did not observe *any* reduced clinical effectiveness of the VCDs that were later recalled."). Dr. Flack need

not know which of his patients took which VCDs to reliably reach this opinion.[1] *See, e.g., O'Bryant v. Johnson & Johnson*, 2022 U.S. Dist. LEXIS 187758, at *17 (D.N.J. October 13, 2022) ("One knowledgeable about a particular subject need not be precisely informed about all details of the issues raised in order to offer an opinion.") (citation omitted). And courts in the Third Circuit have recognized that where, as here, "the expert's testimony is based upon personal knowledge and experience, 'the methodology used will be applying that experience to the facts of the case.'" *Stokes v. Janosko*, 2018 U.S. Dist. LEXIS 113826, at *11 (W.D. Pa. July 10, 2018). Plaintiffs do not cite any law to the contrary.

In short, Dr. Flack's testimony related to his clinical experience rests on "good grounds, based on what is known." *See Terry v. McNeil-PPC, Inc. (In re Tylenol (Acetaminophen) Mktg., Sales Practices, & Prods. Liab. Litig.)*, 2016 U.S. Dist. LEXIS 97368, at *5 (E.D. Pa. July 26, 2016). It therefore meets the standard of reliability under Rule 702, and Plaintiffs' motion should be denied.

[1] As Dr. Flack explained, that information would not be available to him (or any other clinician). *See* Flack Dep. 47:14-48:3 ("When I write a prescription, the – the lots that are affected are – can be significant. That is something that the pharmacy handles and – and all. And so we don't go and dig because, one, I don't know what lot they are taking and, No. 2, I doubt if I could really even get this information because the pharmacy doesn't have time to give it to me. They are certainly not going to let me into their records.").

II. DR. FLACK'S OPINION THAT THE VALSARTAN RECALL DID NOT AFFECT PATIENTS' ABILITY TO OBTAIN EFFECTIVE ANTIHYPERTENSIVE MEDICATIONS IS SUPPORTED BY RELIABLE EVIDENCE.

Dr. Flack opines, based on his knowledge and background as a hypertension specialist and researcher with a robust clinical practice treating hypertensive patients and prescribing antihypertensive medications, that the recall did not cause adverse *clinical* outcomes for patients who used these medications because they were still able to obtain effective hypertension treatments. *See* Flack Rep. at 13-14. While Plaintiffs assert that Dr. Flack seeks to testify that "patients taking VCDs were not affected by the recall,[2] *see* Motion § II, Dr. Flack does not offer this opinion, nor does he opine on the risk of cancer associated with use of VCDs containing trace nitrosamines. *See* Flack Dep. 13:13-15 ("I am not here to actually discuss the risk of the valsartan that contained trace – trace nitrosamines.").

Dr. Flack explained that if a patient's antihypertensive medication became unavailable, the patient would need to be prescribed alternative medications to maintain blood pressure control and that the medications that are ultimately chosen as replacements were driven by physicians' judgment based on multiple, individualized factors. *See* Flack. Rep. at 14-15. Dr. Flack also explained that many

[2] In fact, Dr. Flack testified about one impact of the recall on some patients taking antihypertensive medications—that they had concerns and requested to be switched from VCDs to other medications. Flack Dep. 45:16-23.

drugs can be substituted for VCDs, including other ARBs, as well as drugs in other classes, e.g., ACE inhibitors, epithelial sodium channel inhibitors, diuretics, beta blockers, alpha blockers, alpha-beta blockers, central adrenergic inhibitors, or aldosterone antagonists. *Id.* Accordingly, as Dr. Flack testified, there would not have been any issue switching a patient from a VCD to an alternative medication.[3] He explained:

> Changing a patient's medication both within a class and between classes is done every day of the week in clinical practices, my and general practitioners especially practices. We could not really practice medicine without doing that. . . . We change medications, take people off their current meds, put them on others. It is an accepted practice and there is really minimal risk in doing so, very, very minimal risk. So it's routine. It's done with the availability of a number of angiotensin receptor blockers. . . . [E]ven if there weren't any other ARBs, so there is an ACE inhibitor class and other drug classes that you could use, so there were plenty of options, and I think the vast majority of people got this done within the ARB class.

Flack Dep. 66:10-67:10.

Separately, Dr. Flack notes that, *accepting the FDA's estimate on the increased risk of cancer for patients as accurate*, few patients taking recalled VCDs were at any increased risk, given studies on and his personal experience with how hypertensive patients use antihypertensive medications. *See* Flack Rep. at 12-13; *see also* Flack Dep. 24:13-25:20. As Dr. Flack explains in his report, nearly fifty percent

[3] Dr. Flack also testified that valsartan not containing nitrosamines was still available during the recalls. *See, e.g.*, Flack Dep. 22:21-23:6.

of patients who initiate therapy discontinue the initially prescribed medication within one year. *Id*. In other words, Dr. Flack's point regarding patients discontinuing antihypertensive medications is not about the *number* of patients taking VCDs at any given time, as Plaintiffs suggest, but rather about the *duration* for which patients taking any given antihypertensive medication stay on that medication. Thus, any "statistic that recognizes the pool of patients taking valsartan may also grow larger" due to patients switching medications would not be relevant to this opinion. *See* Motion § II.

The one case Plaintiffs cite, *Player v. Motiva Enters. LLC*, 2006 U.S. Dist. LEXIS 2288, *31 (D.N.J. Jan. 20, 2006), is irrelevant because Plaintiffs have pointed to no evidence that Dr. Flack's *actual* opinions are the product of cherry-picking.[4] And the *Player* court's grounds for excluding the challenged expert went far beyond cherry-picking. The court found the expert's methodology to be unreliable for multiple reasons (and also found him to be unqualified). *Id.* at *25-31. The expert's method was untestable and arbitrary, was not generally accepted, established, or peer

[4] This Court has also rejected claims of "cherry-picking" as a basis for exclusion of experts' opinions. *See* Transcript of March 2, 2022, Evidentiary Hearing [Doc. 1959] 148:20-149:7 ("[T]his is a complaint that both sides have as to every single expert in this case. And this is about the cherry-picking of the data. But really that's what experts do. They look at the data, they decide and they express their reasons why some data is more important at arriving at their opinions than others. So long as they explain how they come to their opinions, and so long as they attempt to explain why they didn't think contrary data is not relevant to their opinion, then that's not objectionable.")

reviewed, and was employed without any real standards. *Id.* The *Player* case has nothing to do with Dr. Flack's methodology in rendering his opinions about the (lack of any) clinical impact on patients as a result of the valsartan recalls. Plaintiffs' Motion should be denied on this point.

III. DR. FLACK IS QUALIFIED TO GIVE HIS OPINION THAT THIRD-PARTY PAYORS, WOULD HAVE HAD TO PAY FOR ALTERNATIVE MEDICATIONS IF THE RECALLED VCDS HAD BEEN UNAVAILABLE.

Plaintiffs' challenges to Dr. Flack's opinion that third-party payors would have paid for alternative medications had the recalled VCDs been unavailable again miss the mark and are unsupported. Plaintiffs first contend that Dr. Flack is not qualified to render these opinions because he never worked for a third-party payor or health insurance plan or sat on a pharmacy and therapeutics committee of a pharmacy benefits manager and does not discuss what a pharmacy benefits manager reviews and relies on in determining when to pay for a medication. *See* Motion § III. But Dr. Flack does not need to have worked for a third-party payor to offer opinions related to hypertensive patients' need for antihypertensive medications. Again, Dr. Flack has an extensive clinical practice and has treated thousands of patients in his career and prescribed antihypertensive medications to approximately 4,000-5,000 patients between 2012-2018. *See* Flack Dep. 34:6-10. Based on his clinical experience, as well as his experience as researcher and peer-reviewer, Dr. Flack explains that "patients who have been diagnosed with hypertension, especially Stage

2 hypertension, are typically dependent on their prescribed medication regimen in order to effectively control their blood pressure and are rarely able to discontinue medication through lifestyle changes. In other words, if a particular antihypertensive drug is unavailable for any reason, a patient who adheres to their prescribed treatment will almost certainly require and be prescribed an alternative medication or combination of medications." Flack Report at 14. From that foundation, he opines that patients who depended on antihypertensive medications during the time VCDs containing nitrosamines were on the market would have been prescribed other treatments if those VCDs had been unavailable. In doing so, Dr. Flack reliably "appl[ied] [his] experience to the facts of the case.'" *Stokes*, 2018 U.S. Dist. LEXIS 113826, at *11. Again, Plaintiffs cite no law to the contrary.

This opinion also fits the case. Dr. Flack is not seeking to "change the landscape by opining on speculative world," as Plaintiffs suggest. *See* Motion § III. Based on his clinical experience treating hypertension, he does not need to speculate to offer the logical opinion that if the recalled VCDs had been unavailable between 2012 and 2018, third-party payors would have paid for alternative medications. *See* Flack Rep. at 17. This opinion is directly relevant to Plaintiffs' claimed damages, which include the "*full amounts paid or reimbursed for the VCD*s; the costs to replace or return VCDs because of recalls; . . . and/or the increases in the amounts paid for non-adulterated, non-misbranded VCDs in the wake of the recalls." Third

Amended Economic Loss Master Complaint [Doc. 1708] at Prayer for Relief ¶ E; *see also, e.g., AIG Prop. Cas. Co. v. A.O. Smith Corp.*, 2018 U.S. Dist. LEXIS 148273, *8 (D.N.J. Aug. 30, 2018) (explaining that "fit" means that the expert's opinion must be "relevant for the purposes of the case and assist the trier of fact"). Dr. Flack's opinion that third-party payors would have paid for some other medication or combination of medications in lieu of recalled VCDs is plainly relevant to this claim. Plaintiffs' Motion to exclude this opinion should be denied as Dr. Flack is qualified to offer it and it will help the trier of fact decide a key issue.

CONCLUSION

For all these reasons, Defendants respectfully ask the Court to deny Plaintiffs' Motion to exclude Dr. Flack's opinions.

Dated: April 11, 2023

Respectfully Submitted:

By: */s/ Victoria Davis Lockard*

GREENBERG TRAURIG, LLP
Lori G. Cohen
Victoria Davis Lockard
Steven M. Harkins
Terminus 200
3333 Piedmont Road, N.E.,
Suite 2500
Atlanta, Georgia 30305
Tel. (678) 553-2100
Fax. (678) 553-2386
CohenL@gtlaw.com
LockardV@gtlaw.com
HarkinsS@gtlaw.com

Counsel for Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd., Actavis Pharma, Inc., and Actavis LLC

Jessica Davidson (DC Bar No. 457021)
(Admitted to Practice in Maryland and the District of Columbia; Not Admitted in New York)
Liaison Counsel for Manufacturer Defendants
Allison M. Brown
SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP
One Manhattan West
New York, NY 10001 20005
Tel.: (212) 735-2588
Fax: (212) 777-2588
jessica.davidson@skadden.com
Allison.brown@skadden.com

SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP
Nina R. Rose
1440 New York Ave., N.W.
Washington, D.C. 20005
Tel.: (202) 371-7000
Fax: (202) 661-0525
nina.rose@skadden.com

Counsel for Zhejiang Huahai Pharmaceutical Co, Ltd., Huahai U.S., Inc., Prinston Pharmaceutical Inc. and Solco Healthcare U.S., LLC

KIRKLAND & ELLIS LLP
Devora W. Allon
Alexia R. Brancato
601 Lexington Avenue
New York, New York 10022
Tel: (212) 446-5967
Fax: (212) 446-6460
Devora.allon@kirkland.com
Alexia.brancato@kirkland.com

Attorneys for Torrent Pharmaceuticals Ltd. and Torrent Pharma Inc.

CERTIFICATE OF SERVICE

I hereby certify that on April 11, 2023, I caused a copy of the foregoing document to be served on all counsel of record via CM/ECF.

/s/ Steven M. Harkins
Steven M. Harkins
Greenberg Traurig, LLP